## Food and Drug Administration, HHS

- (c) Conditions of use—(1) Dogs—(i) Amount. For dogs 5 pounds and under, 0.3 milliliter (17.0 milligrams); for 6 to 10 pounds, 0.5 milliliter (28.4 milligrams); for 11 to 25 pounds, 1.0 milliliter (56.8 milligrams); if over 25 Pounds, 0.2 milliliter (11.4 milligrams) per 5 pounds body weight to a maximum of 3 milliliters (170.4 milligrams).
- (ii) Indications for use. For removal of canine cestodes Dipylidium caninum, Taenia pisiformis, and Echinococcus granulosus, and removal and control of canine cestode Echinococcus multilocularis.
- (iii) *Limitations*. For subcutaneous or intramuscular use; not intended for use in puppies less than 4 weeks of age; Federal law restricts the drug to use by or on the order of a licensed veterinarian.
- (2) Cats—(i) Amount. For cats under 5 pounds, 0.2 milliliter (11.4 milligrams); 5 to 10 pounds, 0.4 milliliter (22.7 milligrams); 11 pounds and over, 0.6 milliliter (34.1 milligrams) maximum.
- (ii) *Indications for use.* For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis.*
- (iii) *Limitations*. For subcutaneous or intramuscular injection only. Not intended for use in kittens less than 6 weeks of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 10464, Feb. 3, 1981, as amended at 47 FR 6617, Feb. 16, 1982; 58 FR 42853, Aug. 12, 1993; 67 FR 79853, Dec. 31, 2002]

## § 522.1881 Sterile prednisolone acetate aqueous suspension.

- (a) *Specifications*. Each milliliter of sterile aqueous suspension contains 25 milligrams of prednisolone acetate.
- (b) *Sponsor*. See No. 000061 ir §510.600(c) of this chapter.
- (c) NAS/NRC status. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter but may require bioequivalency and safety information.
- (d) Conditions of use. (1) The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations

- such as bursitis, carpitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and post-operatively and for various stress conditions when corticosteroids are required while the animal is being treated for a specific condition.
- (2) The drug is administered to horses intra-articularly at a dosage level of 50 to 100 milligrams. The dose may be repeated when necessary. If no response is noted after 3 or 4 days, the possibility must be considered that the condition is unresponsive to prednisolone therapy. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 milligrams. The dosage may be repeated when necessary. If the condition is of a chronic nature, an oral corticosteroid may be given as a maintenance dosage. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 milligrams. The dose may be repeated when necessary after 7 days for two or three doses.
- (3) The labeling shall comply with the requirements of §510.410 of this chapter for corticosteroids.
- (4) Not for use in horses intended for food.
- (5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 23032, June 17, 1987]

## § 522.1883 Prednisolone sodium phosphate.

- (a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).
- (b) *Sponsor.* See No. 061623 in §510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Administer intravenously in a dosage of 2 1/2 to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.
- (2) Indications for use. Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.